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REMARKS

By this amendment, the non-elected claims as well as claims 8, 19, and 38-40 are canceled and claims 6, 9, 17, 20, 21, 26, 37, and 41 are revised to place this application in condition for allowance. Currently, claims 6, 7, 9, 17, 18, 20, 21, 26, 37 and 41 are before the Examiner for consideration on their merits.

First, the problem with claims 17 and 21 regarding claim dependency have been corrected by amendment.

Second, independent claims 6 and 17 are revised to essentially incorporate the step of claims 8 and 19, respectively, with respect to the dilution of the formed absorption base using preheated water.

In light of the revisions to claims 6 and 17, Applicant respectfully traverses the rejection of the claims based on United States Patent No. 5,951,991 to Wagner et al. (Wagner) and United States Patent No. 4,788,001 to Narula when modified by United States Patent No. 6,153,208 to McAtee et al. (McAtee). The traverse is set out below under the headings of the prior art applied against the claims.

WAGNER

Wagner is fundamentally different from the invention and cannot be used to formulate a rejection under 35 U.S.C. § 103(a).

Wagner describes a 3 component system consisting of an inert woven or sponge-like material (the water insoluble substrate) to act as a substrate for the deposition of a lathering surfactant (foaming, cleansing agent). A third component is a

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conditioning emulsion, which is made up of an internal phase comprising a water soluble conditioning agent and an external phase as an oil soluble agent. The conditioning emulsion can incorporate a vast compendium of ingredients, including drugs. The conditioning emulsifier and the lathering surfactant are deposited onto the substrate in a dry condition, and then deposited on the skin with the aid of a torrent of water such as a shower stream.

Important to understand here is that the entire 3 component system of Wagner must be invoked for the system to work. Wagner, in col. 5, lines 65-68 and col. 6, lines 1-5, states:

The water insoluble substrate is the implement or vehicle for delivering the lathering surfactant and the conditioning component of the present invention to the skin or hair to be cleansed or conditioned. Without being limited by theory, it is believed that the substrate, by providing mechanical agitation provides a lather generating effect and also aids in the deposition of the conditioning component.

In rejecting claims 6 and 17, the Examiner contends that Wagner teaches making a conditioning emulsion (and only by way of listing an enormous list of emulsifiers and oils and ranges of temperature for their preparation and with no actual experiment with these ingredients) that covers the steps recited in claims 6 and 17 as they relate to combining the white petrolatum and addition of methyl glucose dioleate of parameters to produce an absorption base.

However, the stated objective of Wagner is in the context of its use in the 3 component system described above and makes no mention of the pharmaceutical entity known as an absorption base or its utility for skin use alone or as a base to be used with other ingredients. In order to emphasize this difference, claims 6 and 17 are revised to clarify that the emulsified absorption base is intended for these uses. Again, Wagner's

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conditioning emulsifier is not intended for use as an emulsifier absorption base; it is employed in a dry state on a water insoluble substrate.

A second key distinction between Wagner and claims 6 and 17 is the requirement that the absorption base is diluted with preheated water. In the rejection it is not entirely clear as to the reasoning used to address the limitations of claims 8 and 19. It seems that the Examiner is alleging that Wagner teaches the dilution step, just not a dilution step using the claimed temperature, and that controlling the temperature of the water for dilution is an optimization that does not involve a patentable step.

In fact, Wagner does not teach a diluting step as now found in claims 6 and 17, regardless of the temperature limitation. Wagner states that the conditioning emulsion may contain water but only enough to solubilize the water soluble ingredients, see col. 18, lines 65-67. Wagner is also quite clear about restricting the amount of water to less than 3%, see col. 5, lines 14-20. Wagner also describes the addition to the conditioning emulsion of water soluble electrolytes to aid in overcoming the dissolving of lipid components into the water phase if present in too great amount, see col. 19, lines 111-15). Wagner, in col. 1, lines 15-18, also states:

The present invention relates to a substantially dry, disposable, personal cleansing product used by the consumer by wetting the dry product.

Therefore, it cannot be said that Wagner teaches a diluting step to form an emulsified absorption base as is recited in claims 6 and 17. The only teaching by Wagner for the use of water for the conditioning emulsion is when the total 3 part non-woven substrate, the lathering surfactant (foaming agent) and conditioning emulsion are run under a faucet or in a shower. The invention by Wagner is essentially a desiccated delivery system (many methods are described by Wagner to eliminate water from the

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whole invention, see col. 26, lines 34-43). Wagner does not teach how much or under what conditions or what might result from the addition of water to the product other than for wetting purposes or for removal of ingredients by rinsing.

The invention of Wagner is in direct contrast to the present invention, wherein a specified amount of water under specific conditions is added to the inventive and unique absorption base to produce an unexpected result. More exactly, the invention relates to a versatile, lanolin-free absorption base, which can be prepared at room temperature or at any of a wide range of temperatures to accommodate a host of ingredients, e.g., hydrocortisone. The lanolin-free absorption base contains a very small amount of an effective emulsifier and has been found to take up or mix with an equal amount of water and/or other ingredients to make an unusual product which at this stage, while still capable of mixing with small amounts of water, is more correctly referred to as an occlusive base capable of retaining large amounts of skin moisture without causing maceration of the skin. Wagner does not teach the invention of claims 6 and 17 and cannot be said to establish a *prima facie* case of obviousness against claims 6 and 17. Therefore, the rejection must be withdrawn.

The Examiner's citation of the doctrine regarding changing the order of steps of a process as not being a patentable modification to support the rejection regarding the dilution using water makes no sense. It appears that the Examiner has contended that the use of water in the formation of the conditioning emulsion of Wagner (akin to the claimed absorption base) equates to the dilution step when in fact, no such step, i.e., the additional, intentional and controlled addition of water to form the unique occlusive

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base mentioned above, is present in Wagner. Put another way, Wagner does not in the least suggest the claimed dilution step.

The contention that Wagner teaches the step of claims 7 and 18 is also improper. These claims require the addition of a preservative system to the absorption base. While it is true that Wagner discloses the use of the preservative system Glydant Plus; this is only mentioned in preparing the surfactant phase of the invention. This system is not mixed with the conditioning emulsion as stated by the examiner but is rather deposited separately onto a non-woven substrate, see col. 28, lines 25-34 and col. 29, lines 44-47. Since the preservative system is not a part of a component of Wagner's conditioning emulsion, the steps of claims 7 and 18 cannot be said to be taught in Wagner.

Further, the Examiner cannot contend that the method of using the 3-component system of Wagner results in adding the preservative system to the conditioning emulsion. Wagner's method of use involves applying the components incorporated onto the water insoluble substrate onto a user's skin, and this cannot be construed as the same as "adding a preservative system to the absorption base to form a preservative system-containing absorption base" since no base is formed in Wagner's method of using the 3-component system. Therefore, claims 7 and 18 are separately patentable from Wagner.

The rejection of claims 9 and 20 based on Wagner is also traversed. Here, the Examiner contend that it would be obvious to use hydrocortisone or its salts in the invention because it is cited in Wagner as being a possible candidate for deposition under the 3 component system, citing col. 23, line 59. While it is true that Wagner

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identifies hydrocortisone as one of the active ingredients, Wagner offers little more in teaching how it would be incorporated. In fact, Wagner, in col. 21, lines 15-20, admits that the use of the active ingredient is dependent on its compatibility with the internal or external phases of the conditioning emulsion.

Therefore, Applicant questions whether Wagner does teach the step of adding an effective amount of hydrocortisone or a salt thereof to the conditioning emulsion. One of skill in the art knows how insoluble hydrocortisone is and must proceed accordingly. At its best, hydrocortisone is available as a micronized powder from Upjohn and as such, these micronized particles must be dispersed to prevent agglomeration and must dissolve and diffuse to the active site in a time dependent manner as defined by Fick's Law. It is observational but many years after the publication of Wagner, there exists no discernible use of this technology in the pharmaceutical industry which suggests a lack of practicality in the delivery of drugs or other active ingredients using this system. In fact, what drug manufacturer would invest in such a system where the end process is to wash away an expensive drug as is the case with Wagner? Wagner describes a method to measure deposition which involves a 15 sec. rubbing time followed by a 10 sec. rinse. Under this test, only chemicals with a high affinity for skin or hair would survive, see col. 27, lines 39-49. Therefore, it is submitted that Wagner does not teach the steps of claims 9 and 20, and the rejection as applied to these claims must be withdrawn.

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NARULA AND McATEE

The rejection based on the combination of Narula and McAtee is also flawed and these references do not establish a *prima facie* case of obviousness against claims 6 and 17.

The thrust of Narula is to prepare aqueous, liquid emulsions of a mixture of high viscosity silicone fluids, gums and resins using a three part concoction of nonionic surfactants (oil-in-water emulsifying agents with HLBs of 8-16 versus the singular water-in-oil emulsifying agent of the semi-solid invention with an HLB of 5) at room temperature. Narula is singularly interested in producing a feel good product and states in col. 1, lines 60-63:

These emulsions are useful as a substantivity aid in a skin care composition.

A first challenge to the rejection is the allegation that PEG-120 methyl glucose dioleate disclosed in Narula is the same as the claimed methyl glucose dioleate are the same. PEG-120 methyl glucose dioleate differs from the claimed compound by the presence of 120 ethylene oxide units per molecule and an HLB of 16, see col. 6, lines 42-48. This substantially changes the chemical characteristics of the parent molecule. The emulsifying agent of the invention, methyl glucose dioleate, has an HLB of 5. Since the HLB scale only goes to about 18, one can see that there is a serious disparity in the abilities of these molecules in terms of the efficiency of emulsification of petrolatum as will be seen and is noted in the invention. Thus, it cannot be said that Narula teaches either the specific methyl glucose dioleate of claim 6 or the emulsifier of claim 17 having the recited HLB range.

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Moreover, the fact that McAtee may teach another emulsifier does not mean that the non-ionic surfactant having an HLB of 13-15, i.e., PEG-120 methyl glucose dioleate, of Narula could be replaced with another emulsifier so that the claim limitation is met. This is particularly so when considering that the HLB of methyl glucose dioleate is not similar to the target HLB of the nonionic primary surfactant of Narula.

Therefore, regardless of whether McAtee is combined with Narula, these references do not establish a *prima facie* case of obviousness against claims 6 and 17.

A second argument is that Narula does not disclose the claimed heating step. In making the rejection, the examiner cites experiments 11 and 12 of Narula as being definitive in some way. In Experiment 11, no heating is performed and the oil phase having 100 parts of white petrolatum and other components is mixed with the aqueous phase of PEG-120 methyl glucose dioleate and other components. This experiment not only does not heat the petrolatum, but also does not add any water as is now required.

To address the failure of Experiment 11 for heating, the examiner relies on a comparative example of Narula as detailed in col. 8, line 66 to col. 9, col. 9, line 14. In this experiment, an oil phase (a mixture of volatile cyclopolsiloxanes and non-volatile polydimethylsiloxane, which is not petrolatum) is heated to 75 degrees centigrade (this is hot) with PEG-20 methyl sequistearate used as a substitute for PEG-120 methyl glucose dioleate. The emulsion using PEG-20 methyl sequistearate had large sized emulsion particles, which were heated in an attempt to improve the emulsion. Narula reports that heating the oil phase and aqueous phase to 75 °C prior to mixing did not produce any difference in the quality of the emulsion. The comparative example discussed above uses a different oil phase than Experiment 11 and the invention as

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well as a different emulsifier and the teachings of Narula in this regard cannot be imported into Experiment 11. Coupled with the fact that the heating step made no difference, the assertion that Narula teaches that the oil phase should be heated is not supported and is only speculation on the part of the Examiner.

Example 12 does not teach the heating step. While Example 12 does teach a dilution step, this does not overcome the failings of Narula in not teaching the claimed emulsifier of claims 6 and 17, nor the preheating of the diluting water. While the Examiner contends that the preheating limitation is an optimization of a result effective variable, the variable must first be recognized as a result effective one before it can be optimized. Narula says nothing about preheating the diluting water so how can it be said that the preheating in the claims is an optimization. In fact, there is no mention of this step in Narula and the absence thereof precludes the Examiner from characterizing this limitation as an optimization.

Put another way, Narula is fundamentally different from the invention of claims 6 and 17 and does not teach the method of making the emulsified base by heating white petrolatum up to 80 °C , adding methyl glucose dioleate for the purpose of making an absorption base and diluting the absorption base with water preheated up to 50 °C.

The rejection is also flawed when attempting to remedy the failings of Narula by citation to McAtee. It is not entirely clear as to what teachings of McAtee are being relied upon. In the paragraph spanning pages 4 and 5 of the Action, McAtee is cited for teaching heating the emulsion. In the last paragraph of page 5, McAtee seems to be relied upon to teach that it would be obvious to add a preservative and active agent to the emulsion of Narula.

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Nevertheless, Applicant asserts that given the vast differences between Narula and McAtee, one of skill in the art would not be led to the modification of Narula as asserted in the rejection. McAtee is similar to Wagner in its teachings of a 3-component system and is not in the least similar to the system of Narula. As pointed out above, Narula is concerned with emulsifying high viscosity silicone fluids, whereas McAtee is concerned with a 3-component dry system. Just because McAtee may have disclose some features of the invention does not mean that one can automatically conclude that these features could be implemented into Narula. It is respectfully submitted that the Examiner is modifying Narula in an arbitrary fashion to formulate the rejection, and, in reality, there is no legitimate reason to pluck the features used in McAtee and employ them in the teachings of Narula.

Said another way, the Examiner has drawn conclusions of obviousness without any reason to do so. What the Examiner has done is to cite various aspects of McAtee and then state that it would be obvious to make changes to Narula given McAtee. This approach lacks a reason why one of skill in the art would employ the active ingredients and preservatives of McAtee in Narula.

In conclusion, the complex system of emulsification as described by Narula would be impractical, expensive and not scientifically possible to produce an absorption base as described in the invention. Narula makes no claims as to the long term stability of these liquid emulsions or for their moisturizing capability. Narula also makes no claims for the utility of these emulsions when combined with active ingredients such as drugs. Thus the teachings and experiments of Narula are not in anyway equivalent to the invention or in being useful in teaching one skillful in the arts. McAtee is entirely

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unrelated to Narula and it is not proper to merely find features of the invention missing in Narula and conclude obviousness based on their mere existence in McAtee. To rely on McAtee is the use of hindsight and the rejection is tainted for this reason.

Therefore, the rejections of claims 6 and 17 as well as their dependent claims based on Narula and McAtee are improper as failing to establish a *prima facie* case of obviousness.

SUMMARY

To recap, Wagner does not establish a *prima facie* case of obviousness against claims 6, 7, 9, 17, 18, and 20. The other claims rejected based on Wagner are patentable based on their dependency to either claim 6 or claim 17.

Narula and McAtee do not establish a *prima facie* case of obviousness against claims 6 and 17 since Narula does not teach all of the features of these claims, and the missing components are not supplied by McAtee. Further, there is no legitimate reasoning to pick bits and pieces of McAtee to modify Narula without using hindsight. The other claims rejected based on Narula and McAtee are patentable based on their claim dependency.

Accordingly, the Examiner is requested to examine this application in light of this response and pass all claims onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

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The above constitutes a complete response to all issues raised in the Office

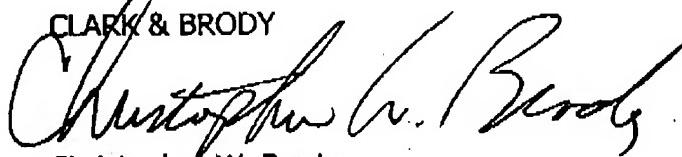
Action dated March 8, 2007.

A petition for a three month extension of time is made. Please charge Deposit Account No. 50-1088 \$510.00 to cover the cost of the petition fee.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,

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